

# BEST AVAILABLE COPY

Application No.: 09/736051

Docket No.: PC9344BRTR (121\*254)

## REMARKS

Applicants respectfully thank the Examiner for the reconsideration and withdrawal of the prior rejections and objections, and for indicating that claims 1-4, 6-14, 16-30, 33-42, 45-50, 52-55, 57-62, 65-69 and 72 are allowable over the prior art. Now pending are claims 1-4, 6-14, 16-30, 33-42, 45-50, 52-55, 57-62, 65-69, 72-75, 79-80, 84-89, and 92-108.

Claims 73-75, 79-80, 84-89 and 92-108 stand rejected under 35 U.S.C. § 103 (a) as rendered obvious by US Patent 6,110,932 (Carpino et al.). Applicants respectfully traverse for the following reasons.

The Patent Office applies Carpino et al. as prior art under 35 U.S.C. § 102(a), citing the Carpino et al. issuance date of August 29, 2000 for its availability as prior art. Office Action, p. 3. Applicants respectfully submit that their priority document, US Pat. App. Ser. No. 60/012,412 filed February 28, 1996, renders Carpino et al. ineffective as prior art under section 102(a) as the Patent Office has asserted. The priority document shows that the invention of Applicants' claims was made before the publication of the Carpino et al. patent on August 29, 2000. Specifically, current claims 73-75, 79-80, 84-89 and 92 are supported in the priority document by the claims of corresponding number. Current claims 93-108 are supported in the priority document as follows: Claim 93: p. 1, ll. 1-3, p. 16, ll. 10-11 and p. 32, ll. 26-30; Claim 94: p. 33, ll. 6-8; Claim 95: p. 5, ll. 17-18; Claim 96: p. 21, ll. 31-32; Claims 97-101: p. 4, ll. 17-20; and Claim 102: p. 4, ll. 17-18, p. 16, ll. 10-12, p. 30, ll. 2-4, and p. 47, l. 33 to p. 48, l. 4.

Applicants' claims for priority under 35 U.S.C. §§ 119(e) and 120 are noted on the filing receipt, so it is believed that the priority documents are available for the Examiner's review on the PTO databases. Nevertheless, a courtesy copy of U.S. Patent Application Serial No. 60/012,412 is enclosed. Acknowledgment of Applicants' claims for priority is respectfully requested.

Applicants additionally traverse the obviousness rejection of Claims 73-75, 79-80, 84-89 and 92 because elements of these claims are not found in the one cited reference, Carpino et al. These claims recite compositions, methods and a kit comprising growth hormone. In contrast,

Carpino et al. discloses novel growth hormone secretagogues and inventions encompassing these secretagogues. Growth hormone secretagogue refers to a compound that stimulates the release of growth hormone or mimics the action of growth hormone. Specification, p. 32, ll. 27-29. As discussed in Carpino et al., growth hormones are not therapeutically the same as growth hormone secretagogues. Carpino et al. report that therapy with growth hormone secretagogues has advantages over therapy with growth hormones. Because growth hormone secretagogues act along physiologic regulatory pathways, they stimulate pulsatile growth hormone secretion and excessive levels of growth hormone that have been associated with the undesirable side effects of exogenous growth hormone administration can be avoided by virtue of intact negative feedback loops. Carpino et al., col. 1, l. 63 to col. 2, l. 5.

The Examiner cites sections of Carpino et al. that refer to combination therapy "with a compound of Formula I." *See, e.g.*, Office Action, p. 4, l. 2. Yet Carpino et al. disclose that the compounds of Formula I are growth hormone secretagogues, not growth hormones. *See, e.g.*, Abstract, col. 20, ll. 7-11 and col. 25, ll. 5-7.

In support of the obviousness rejection, the Patent Office has only cited one reference, the Carpino et al. patent. Because Carpino et al. fails to teach combination therapy with a growth hormone, it is respectfully urged that the rejection of claims 73-75, 79-80, 84-89 and 92 be reconsidered and withdrawn.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 03-2775, from which the undersigned is authorized to draw.

Dated: September 24, 2004

Respectfully submitted,

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